



*On the leading edge of women's health*

February 6, 2004

Mark B. McClellan, MD, PhD  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Mark,

On behalf of the National Association of Nurse Practitioners in Women's Health (NPWH), I am writing to support making Plan B® emergency contraception available over-the-counter, with no restrictions.

Emergency contraception (EC) has the potential to reduce unintended pregnancy and abortion in half. Our members have been prescribing emergency contraception for a number of years. However, we have limitations for being able to provide this prescription to women when they need it. Time is of the essence in maximizing the enormous potential of EC. Taken within 72 hours after unprotected sex or birth control failure, Plan B reduces the average risk of pregnancy by 89%.

Unfortunately, EC is difficult to obtain within the short window of effectiveness. Many health care providers are not available on weekends or evenings when emergency contraception is often needed most. While 72 hours is generally cited as the time frame for effective use, there are scientific data that show the sooner emergency contraception is taken after exposure the greater the effectiveness. It simply does not make good health care sense to make women wait for something when that wait makes it less effective. Major health care professional organizations and indeed, the FDA's own advisory committee, feel Plan B is safe to be provided over-the-counter.

As health care professionals who want the best care provided to women, we fully support making Plan B available over-the-counter. Over-the-counter availability puts this safe and effective drug where women can access it the soonest—in their local drug store where there is no wait for an appointment or for an office to open on Monday morning.

We have attached our position paper on over-the-counter status for emergency contraception that outlines further details about our position.

OIP: 00755

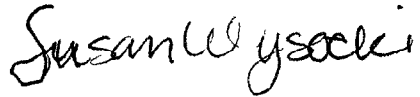
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National Association of Nurse Practitioners in Women's Health

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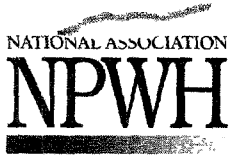
We urge you to approve Plan B for over-the-counter status without delay.

Sincerely,

A handwritten signature in black ink that reads "Susan Wysocki". The signature is written in a cursive, flowing style.

Susan Wysocki, RNC, NP, FAANP  
President and CEO

enclosure



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## **POSITION STATEMENT OVER THE COUNTER STATUS FOR PLAN B EMERGENCY CONTRACEPTION**

*Founded in 1980, the mission of the National Association of Nurse Practitioners in Women's Health (NPWH) is to assure the provision of quality health care to women of all ages by nurse practitioners. NPWH defines quality health care to be inclusive of an individual's physical, emotional, and spiritual needs.*

*NPWH recognizes and respects women as decision-makers for their health care. NPWH's mission includes protecting and promoting a woman's right to make her own choices regarding her health within the context of her personal, religious, cultural, and family beliefs.*

Over the counter status for Plan B emergency contraception assures that a safe and effective product is accessible to women when they need it. The safety and efficacy of this product is well documented. In addition, studies demonstrate that the efficacy of this product is greater when it is taken soon after unprotected intercourse. Over the counter availability would ensure women access to Plan B within a short time frame, thus increasing its effectiveness.

Over the counter status recognizes women's intelligence and foresight to use the product as needed and as directed, and supports their right to self determination. Existing evidence does not support the concern that women will misuse this product if it is available without a prescription.

Over the counter status for Plan B emergency contraception reflects NPWH core value of recognizing and respecting women as decision makers for their health. Therefore, NPWH supports the switch from prescription to over the counter status for Plan B ® emergency contraceptive pills without reservation.

### **References:**

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Jackson, RA, Schwarz, EB, Freedman, L, & Darney, P. (2003). Advance supply of emergency contraception: Effect on use and usual contraception – a randomized trial. Obstetrics & Gynecology, 102(1), 8 – 16.

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Raymond, EG, Chen, P, & Dalebout, SM. (2003) "Actual use" study of emergency contraceptive pills provided in a simulated over the counter manner. Obstetrics & Gynecology, 102(1), 17-23.